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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/560,790

12/15/2005

Peter Ghosh

10682.0010USWO

4918

23552 7590 01/07/2009
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EXAMINER

CARLSON, KAREN C

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

01/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,790	Applicant(s) GHOSH, PETER	
	Examiner Karen Cochran Carlson	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-66 is/are pending in the application.
- 4a) Of the above claim(s) 35-64 and 66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-34 and 65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2006; 2007</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Notice to Comply SEQ</u> . |

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Applicant's election with traverse of Group 2, Claims 29-34, in the reply filed on October 3, 2008 is acknowledged. The traversal is on the ground(s) that the restriction was done using US practice and not PCT practice. Applicants urge that the Groups are linked by the same special technical feature which is the peptide fragments of the collagen type IX alpha chain 1 NC4 domain. The Examiner has rejoined all of the sequences of Claims 29-34. Because art has been found on the claims, the special technical feature is lost. The method claims will remain be rejoined in accordance to In re Ochiaie. Otherwise:

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-28 have been cancelled. The Examiner has withdrawn Claims 35-64 and 66 from further consideration because these claims are drawn to non-elected inventions. Claims 29-34 and 65 are currently under examination.

Benefit of priority is to June 17, 2003.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. See the sequences set forth at 20+ of the

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specification and the newly added sequences which have not been provided in the sequence listing or in the CRF.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29, 33, 34, and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33, 34, and 65 do not appear to have antecedent basis in Claim 29. Claim 29 is drawn to polypeptide fragments having 65% identity to the 245 amino acid SEQ ID NO: 14, and SEQ ID NO: 14 itself is a peptide fragment. However, these dependent claims are drawn to peptides of about 15-22 amino acids which is less than 10% identity over the entirety of SEQ ID NO: 14. Therefore, either Claim 29 is indefinite because the 65% identity is taken over the entirety of SEQ ID NO: 14 unless Applicants intend otherwise by the dependent claims, or dependent Claims 33, 34, and 65 have not antecedent basis in Claim 29.

The rejections below take both interpretations of Claim 29 into consideration.

Additionally, in Claims 33, 34, and 65 it is not clear if the claimed oligopeptides are in the composition in addition to the peptide SEQ ID NO: 14 of Claim 29.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33, 34, and 65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 33, 34, and 65 as drawn to SEQ ID NO: 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, and 32, was entered October 3, 2008. Applicants did not provide a basis for these new sequences (or a new sequence listing and CRF) and the Examiner has not found these sequences in the specification, not even in Figure 9 which appears to teach alternative amino acids for specific positions. Therefore, these sequences are considered to be new matter and should be removed from the claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Vaughan-Thomas et al. (2001; EMBL AF419343).

Vaughan-Thomas et al. teach the NC4 domain or fragment of bovine type IX collagen in articular cartilage having an amino acid length of 187. This sequence shares 70.5% identity with instant SEQ ID NO: 14 over the entire length of SEQ ID NO: 14, and

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is a fragment of having 91.4% identity over the 187 amino acids of the NC4 domain.

The NC\$ domain has a molecular weight of 20.9 kD. It appears that this peptide sequence is in hand because the citation does not state that the sequence is deduced from cDNA, for example. Therefore, the peptide was inherently placed into a composition.

Therefore, Vaughan-Thomas et al. teach a composition comprising a polypeptide fragment having at least 65% amino acid identity to SEQ ID NO: 14 (**Claim 29**), wherein the fragment has an amino acid of less than 30 kD or between 10 and 30 kD (**Claim 30**), wherein the fragment has an amino acid length of less than 250 amino acids (**Claim 31**), wherein the sequence identity to SEQ ID NO: 14 is at least 80% and at least 90% (**Claim 32**).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al. (1990; WO 90/08195).

Olsen et al. teach Glu-Tyr-Ser-Phe-Leu-Thr-Thr-Phe-Arg-Met-Thr-Gly, an oligopeptide epitope in human type IX collagen (page 7). This oligopeptide is found at amino acid 86+ of SEQ ID NO: 14. Olsen et al. do not actually place this oligopeptide into a composition. However, Olsen et al. teach that these oligopeptides can be coupled

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to a carrier protein and be used as antigens for the production of monoclonal antibodies. In Examples 1 and 2 of Olsen et al., Olsen et al. exemplifies this procedure using two other oligopeptides shown on page 3.

It would have been obvious for a person having ordinary skill in the art to place the Glu-Tyr-Ser-Phe-Leu-Thr-Thr-Phe-Arg-Met-Thr-Gly (**Claim 31**) oligopeptide having 100% identity to a portion of SEQ ID NO: 14 into a composition for administration to animals to generate monoclonal antibodies because Olsen et al. teach that this oligopeptide is useful for generating antibodies against type IX collagen and demonstrate the predictability of success using two other oligopeptides (**Claim 29, 32**). A peptide of this size is expected to have a molecular weight of less than 30 kD (**Claim 30**).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen Cochrane Carlson/
Primary Examiner, Art Unit 1656